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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BURKHART, MICHAEL D	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,036	THASTRUP ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/29/2006 has been entered.

Claim Objections

Claim 48 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 48 recites that the substance to be screened in claims 44-46 may be a chemical compound. Absent evidence to the contrary, all substances to be screened must be chemical compounds, i.e. they are composed of atoms. There appears to be no instance where a substance to be screened is not a chemical compound.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 44-46 (from which all other claims depend) have been amended to recite steps of incubating cells with "at least one substance of the library of substances" (in step (b)) and "screening the at least one substance of the library of substances for biological function or biological effect" (in step (c)). The response does not indicate where support for the amendment may be found in the specification. A review of the specification reveals the only libraries disclosed are a compound library in ¶ [0027] of the published application (US 20030082564 A1) and a compound drug library in ¶ [0103]. The recitation of a library of substances is much broader than either of the disclosure of the two compound libraries. A compound implies a level of purity (e.g., "a pure substance composed of two or more elements whose composition is constant", as taken from the *Random House Unabridged Dictionary*, 2006) whereas a substance does not (e.g., "physical matter or material", *ibid.*). Furthermore, there is no disclosure of a method step wherein at least one member of a compound library (or a library of substances) is incubated with the cells of the invention, nor a method step of screening at least one member of a compound library (or a library of substances) for a biological effect or function. Therefore, there appears to be no support for the amended claims, and there is no evidence that applicants considered methods steps of: 1) at least one substance from a library of substances was incubated with the cells of the invention; or, 2) at least one substance from a library of substances was

screened for a biological function or effect, as a part of their invention. Thus, the amended claims include impermissible New Matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44-46 have been amended to recite substances having "unknown influences" on the translocation of a subunit. To whom is the influence to be unknown? If the skilled artisan practicing the claimed invention did not know the influence of a particular substance, yet a colleague did, would the skilled artisan be infringing the instant invention? The same is true for the inverse situation, wherein the artisan practicing the invention was aware of the influence, yet the colleague was not, does this constitute infringement of the claims? Thus, the metes and bounds of the claimed invention are ambiguous. This rejection affects all dependent claims.

Claim 53 recites the limitation "the group of GFPs" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Carey et al (J. Cell Biol., June 1996, cited by applicants in the IDS of 2/5/2002). **This rejection is maintained for reasons made of record in the Office Action of 12/1/2005 and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 8/29/2006 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) Carey et al do not teach the screening of a compound with an "unknown influence" for a biological effect because the effect of dexamethasone on GR was known; 2) Carey et al do not teach the screening of a library of compounds for an effect.

Regarding 1), the effect of dexamethasone on GR-GFP was not known at the time, that is why Carey et al did the experiments. Regarding 2), there is no definition of a "library of substances" or a "library of compounds" in the specification, thus the phrases are open to a broad interpretation. Furthermore, the claims only require that at least one substance be screened for an effect. Thus, the one substance is dexamethasone, and the library of compounds/substances is considered to be any and all substances mentioned in the Materials and Methods section on pages 986-987, phenol red and serum. Phenol red and serum are taught to affect the subcellular distribution of GR (¶ linking first and second columns, page 987), and their affect on GR-GFP was unknown. Thus, at a minimum, a library of substances taught by Carey et al comprises

dexamethasone, phenol red, and the compounds contained in serum. Out of this library, Carey et al measured the effect of dexamethasone for reasons made of record. Furthermore, the affects of charcoal-stripped serum on GFP-GR were also measured (see page 986, second column, first full ¶). Thus, the teachings of Carey et al are still considered anticipatory of the claimed invention.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carey as applied to claims 44-52 above, and further in view of Cormack et al (Gene, 1996). **This rejection is maintained for reasons made of record in the Office Action of 12/1/2005 and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 8/29/2006 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) Cormack et al does not teach the limitations of screening a compound to determine if the compound is biologically active; 2) Cormack et al does not teach the limitations of screening a library of compounds to determine if the library contains a compound that is biologically active, thus Cormack et al does not cure the deficiencies of Carey et al.

Regarding both 1) and 2), Cormack et al is not relied upon to cure the deficiencies of Carey et al, which anticipates claims 44-52 for reasons outlined above. Thus, the invention of claims 53 and 54 is still rendered obvious by Carey et al in view of Cormack et al.

Double Patenting

Claim 49 is objected to under 37 CFR 1.75 as being a substantial duplicate of claims 44-46. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 44-46 recite methods of screening substances for a biological effect or function that have unknown influences on the intracellular translocation of a subunit. Thus, by definition, the limitation of claim 49, "wherein...a substance whose affect on an intracellular pathway is to be determined" is within independent claims 44-46

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER

Michael D. Burkhart
Examiner
Art Unit 1633